

**Appl. No.** : **10/649,480**  
**Filed** : **August 27, 2003**

## **SUMMARY OF INTERVIEW**

### Exhibits and/or Demonstrations

none

### Identification of Claims Discussed

Claim 1

### Identification of Prior Art Discussed

Fasol, et al. (J. Thorac. Cardiovasc. Surg. 1994, Vol. 107: 1432-1439)

Ellis (US Patent No. 6,045,565)

### Proposed Amendments

An amendment to claim 1 was proposed which included a step of evaluating at least one clinical index of cardiac function to confirm that cardiac efficiency has increased.

### Principal Arguments and Other Matters

Fasol, et al. and Ellis are the closest prior art. Neither reference tests in humans. Neither reference indicates that cardiac efficiency has increased as result of treatment. Neither reference teaches injection into an ischemic region.

The claims recite injection into an ischemic region. The claims have been additionally amended to recite an increase in cardiac efficiency which results from the treatment and a step of evaluating a clinical index of cardiac function to confirm that cardiac efficiency has increased.

While it may have been obvious to try to inject FGF into an ischemic region at the time of the claimed invention, it was argued that there was no reasonable expectation of success. In fact, Fasol, et al. conclude at page 10, paragraph 3 that "we do not have any information concerning the hemodynamic significance of these new blood vessels in supplying blood to the heart". While Fasol, et al. demonstrate neoangiogenesis, there is no likelihood of success that this neoangiogenesis would have clinical significance. Furthermore, there is no likelihood of success that injection into an ischemic region would produce neoangiogenesis as taught by Fasol, et al. because Fasol, et al. do not inject into an ischemic region. A region having necrotic tissue and/or unhealthy tissue might not be capable of neoangiogenesis.

Applicant's representative also mentioned unpredictability as evidenced by Banai, et al.

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Results of Interview

Applicants will cancel claims 12, 17, and 37.

Applicant will submit their proposed amendment and written arguments.